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EXAMINER	
ANDERSON, JAMES D	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/826,679	BALENDIRAN, GANESARATNAM K.	
	Examiner	Art Unit	
	James D. Anderson	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) *1-5 and 11-13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-10* is/are rejected.

7)☒ Claim(s) *6,8 and 10* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 April 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *14 sheets*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group II, claims 6-10, in the reply filed on 3/27/2007 is acknowledged. The traversal is on the ground(s) that the claims of Groups I-III are not mutually exclusive. This is not found persuasive because aldose reductase inhibitors can be used for other purposes aside from treating neoplasms as recited in the claims of Group II. For example, aldose reductase inhibitors are being studied in the prevention of eye and nerve damage in patients with diabetes. Further, as recited in the Restriction Requirement, the scope of the claims of Groups I-III does not overlap and the claimed inventions have different designs and effects. For example, the claims of Group I require administration to a subject whereas the claims of Groups II and III do not and the claims of Groups I and II require modulating the activity of aldose reductase whereas the claims of Group II do not have this requirement.

The requirement is still deemed proper and is therefore made **FINAL**.

Claims 1-5 and 11-13 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 3/27/2007.

Applicant's election with traverse of: A) carcinomas as one specie of neoplasm; B) gemfibrizil as one species of fibrate; and C) doxorubicin as one species of chemotherapeutics in the reply filed on 3/27/2007 is acknowledged. The traversal is on the ground(s) that it would not present an undue search burden on the Examiner to examine the full scope of the claimed

invention. This argument is persuasive and the Election of Species Requirement is hereby withdrawn.

Status of the Claims

Claims 1-13 are currently pending and are the subject of this Office Action. Claims 1-5 and 11-13 are withdrawn from consideration pursuant to 37 CFR § 1.142(b). Claims 6-10 are presently under examination.

Priority

This application claims priority to U.S. Provisional Patent Application No. 60/463,629 filed April 16, 2003. No support is found in the priority document for the instantly claimed method of treating a neoplasm by administering a fibrate. As such, the earliest effective U.S. filing date afforded the claimed invention has been determined to be 4/16/2004, the filing date of the instant application.

Information Disclosure Statement

Receipt is acknowledged of the Information Disclosure Statement filed 4/21/2005. Examiner has reviewed the references cited therein to the extent that each is a proper citation. Please see attached USPTO Form 1149.

The listing of references in the specification is not a proper information disclosure statement. 37 CFR § 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be

incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Drawings

The drawings are objected to as failing to comply with 37 CFR § 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: for example, Figure 9 has panels labeled A-D, however the Brief Description of the Drawing does not identify what is shown in each panel. Corrected drawing sheets in compliance with 37 CFR § 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR § 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR § 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

Claim 6 is objected to because of the following informalities: it appears the word ---a--- is missing between the words "with" and "fibrate" in line 2. Appropriate correction is required.

Claim 8 is objected to because of the following informalities: it appears the word "gemfibrizil" is misspelled. The correct spelling is ---gemfibrozil---. Appropriate correction is required.

Claim 10 is objected to because of the following informalities: it appears the word "chemotherapeutics" in line 2 should be the singular "chemotherapeutic". Appropriate correction is required.

Claim Rejections - 35 USC § 112 (2nd Paragraph)

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6-10 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In the instant case, claims 6 and 10 recite the limitation "comprising a step of..." in line 1 of each respective claim. This limitation is indefinite because it is not clear if other steps are intended to follow this step, and if so, what those steps are. Amending claims 1 and 10 by deleting the phrase "a step of" will overcome this rejection.

Claim Rejections - 35 USC § 112 (1st Paragraph)

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6 and 9-10 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a Written Description Rejection.

The claims are drawn to administering a "fibrate". The specification discloses examples of fibrates (*e.g.*, page 7, ¶ [0014]), which include clofibric acid, ciprofibrate, gemfibrozil, bezafibrate, fenofibrate and their analogues. The specification does not disclose any other fibrates or their analogues as broadly encompassed in the claims.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In the instant case, the only factor present in the claims is a recitation of "fibrate". Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Although drawn to the DNA arts, the findings in *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997) and *Enzo Biochem, Inc. v. Gen-Probe Inc.* are relevant to the instant claims. The Federal Circuit addressed the application of the written description requirement to DNA-related inventions in *Lilly*. The court stated that, "[A] written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name', of the claimed subject matter sufficient to distinguish it from other materials. " *Lilly* at 1567, 43 USPQ2d at 1405. The court also stated that:

> "[A] generic statement such as 'vertebrate insulin cDNA' or 'mammalian insulin cDNA' without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is." *Id.* at 1568, 43 USPQ2d at 1406.

The court concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." *Id.*

Finally, the court addressed the manner by which a genus of cDNAs might be described. "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." *Id.*

The Federal Circuit has recently clarified that a DNA molecule can be adequately described without disclosing its complete structure. See *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002). The *Enzo* court adopted the standard that

"the written description requirement can be met by show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics, *i.e.*, complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics." *Id.* at 1324, 63 USPQ2d at 1613 (emphasis added, bracketed material in original).

While the inventions at issue in *Lilly* and *Enzo* were DNA constructs *per se*, the holdings of those cases are also applicable to claims such as those at issue here (which are drawn to fibrates). The instant specification may provide an adequate written description of fibrates, per *Lilly*, by structurally describing representative fibrates (*e.g.*, specific compounds), or by describing "structural features common to the members of the genus, which features constitute a substantial portion of the genus." Alternatively, per *Enzo*, the specification can show that the claimed invention is complete "by disclosure of sufficiently detailed, relevant identifying characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics."

In this case, the specification does not directly describe fibrates or their analogues useful in the claimed invention in a manner that satisfies either the *Lilly* or *Enzo* standards. Although the specification discloses five specific compounds and identifies these compounds as fibrates, this does not provide a description of the broadly claimed fibrates that would satisfy the standard set out in *Enzo* because the specification provides no functional characteristics coupled to structural features (*i.e.*, what structural features, for example, make a compound a "fibrate"). It is noted fibrates are structurally diverse and have no common structural core. Further, the

specification also fails to describe fibrates by the test set out in *Lilly* because the specification describes (by name) only clofibric acid, ciprofibrate, gemfibrozil, bezafibrate and fenofibrate. Therefore it necessarily fails to describe a representative number of such species.

Thus, the specification does not provide an adequate written description of fibrates or their analogues that is required to practice the claimed invention, other than those five species named in the disclosure.

Claims 6-10 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is an Enablement Rejection.

To be enabling, the specification of the patent application must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557, 1561 (Fd. Cir. 1993). Explaining what is meant by "undue experimentation," the Federal Circuit has stated that:

> The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which experimentation should proceed to enable the determination of how to practice a desired embodiment of the claimed invention. PPG v. Guardian, 75 F.3d 1558, 1564 (Fed. Cir. 1996).[1]

[1] As pointed out by the court in *In re Angstadt*, 537 F.2d 498 at 504 (CCPA 1976), the key word is "undue", not "experimentation".

The factors that may be considered in determining whether a disclosure would require undue experimentation are set forth by *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 wherein, citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,

2) the amount of direction or guidance provided,

3) the presence or absence of working examples,

4) the nature of the invention,

5) the state of the prior art,

6) the relative skill of those in the art,

7) the predictability of the art, and

8) The breadth of the claims.

These factors are always applied against the background understanding that scope of enablement varies inversely with the degree of unpredictability involved. *In re Fisher*, 57 CCPA 1099, 1108, 427 F.2d 833, 839, 166 USPQ 18, 24 (1970). Keeping that in mind, the Wands factors are relevant to the instant fact situation for the following reasons:

1. The nature of the invention, state and predictability of the art, and relative skill of those in the art

The invention relates to the treatment of neoplasms (claim 6), including tumors, cancers, fibromas, melanomas, carcinomas, adenocarcinomas, sarcomas, lymphomas, and leukemias

(claim 10). The treatment method involves contacting a neoplasm with a fibrate such as bezafibrate (claim 7), ciprofibrate, gemfibrozil or fenofibrate (claim 8). Fibrates are well known in the art as lipoprotein lipase activators and hypolipidemic drugs. Applicant's invention is based on the discovery of a previously unknown mechanism of action of fibrates, namely inhibition of aldose reductase (Table 1). It has been demonstrated in the prior art that aldose reductase activity is increased in cancer cells but there is no direct or indirect evidence that such an increase is involved in the pathophysiology of cancer.

The relative skill of those in the art is high, generally that of an M.D. or Ph.D. That factor is outweighed, however, by the unpredictable nature of the art.

Fibrates have been administered in preclinical *in vitro* and *in vivo* models of cancer. For example, Mulligan *et al.* (Br. J. Cancer, 1991, vol. 64, pages 1035-1038) administered bezafibrate to animals with MAC16 tumors (Abstract). It is clear from the data (Figure 1 and Table 1) that bezafibrate had no effect on tumor volume *in vivo* or the growth of MAC16 tumors *in vitro*. Similarly, Saidi *et al.* (Molecular Cancer, 2006, vol. 5, pages 1-14; printed from http://www.molecular-cancer.com/content/5/1/13 on 4/17/2007) discuss the *in vitro* and *in vivo* effects of fenofibrate and retinoic acid in endometrial cancer (Abstract). While fenofibrate inhibited endometrial cancer growth *in vitro*, no such effect was observed *in vivo* (Abstract). The authors conclude that development of an appropriate animal model remains essential to demonstrating the applicability of the fenofibrate and retinoic acid combination in the treatment of endometrial cancer (pages 12-13). Grabacka *et al.* (Arch. Dermatol. Res., 2004, vol. 296, pages 54-58) studied the effects of fenofibrate in the inhibition of melanoma metastases (Abstract). Fenofibrate showed no effect on melanoma tumor growth *in vivo* (Figure 2A).

Tsubouchi *et al.* (Biochemical and Biophysical Research Communications, 2000, vol. 270, pages 400-405) studied the effects of PPARγ and PPARα agonists in the inhibition of human lung cancer cell growth *in vitro* (Abstract). The fibrate bezafibrate (a PPARα agonist) did not reduce lung cancer cell proliferation (Figure 2). In fact, bezafibrate appears to have increased proliferation of lung cancer cells (Figure 3). Finally, Newman *et al.* (JAMA, 1996, vol. 275, pages 55-60) reviewed the findings of studies of rodent carcinogenicity of lipid-lowering drugs. All members of the two most popular classes of lipid-lowering drugs (the fibrates and the statins) cause cancer in rodents, in some cases at levels of animal exposure close to those prescribed to humans (Abstract). For example, both clofibrate and gemfibrozil increased benign and malignant liver tumors in rats and mice (Table 1).

There have also been studies in the prior art wherein fibrates have demonstrated some efficacy in *in vitro* cancer cell proliferation and *in vivo* tumor growth. For example, Scatena *et al.* (Cell Death and Differentiation, 1999, vol. 6, pages 781-787) administered bezafibrate and gemfibrozil to the human leukemia-dreived cell lines HL-60, U-937 and K-562 (Abstract). The results show that these fibrates induce differentiation and significantly alter cell cycle distributions (Abstract; Figures 1-6). Nomura *et al.* (Surg. Today, 1996, vol. 26, pages 89-94) administered bezafibrate to tumor-bearing mice (Abstract). The results show that after 30 days, tumor growth was suppressed compared to the untreated group (Figure 3). However, this result was due to changes in metabolic pathways resulting from bezafibrate administration, not from direct action of the drug on the tumor (page 93).

It is clear from the prior art discussed *supra* that the administration of fibrates to treat neoplasms is extremely unpredictable and that no mechanism of action can fully account for the

diverse responses seen in treating various neoplasms. Further, there is evidence that administration of fibrates actually induces cancer in some animal models. As such, the skilled artisan cannot predict with any reasonable certainty which fibrates will be effective to treat which neoplasms.

2. The breadth of the claims

The claims are extremely broad insofar as they disclose the general treatment of neoplasms with a broad genus of compounds (fibrates).

3. The amount of direction or guidance provided and the presence or absence of working examples

The specification provides no direction or guidance for determining the particular administration regimens (*e.g.*, dosages, timing, administration routes, etc.) necessary to treat all of the various neoplasms claimed, particularly in humans. The working examples are limited to demonstrating that fibrates inhibit aldose reductase activity. However, as discussed *supra*, the prior art does not recognize a correlation between aldose reductase activity and cancer. While there is some evidence that aldose reductase activity is increased in some cancers, there is no evidence that such an increase in activity is related to carcinogenesis or that inhibiting aldose reductase activity will have any beneficial effect in treating a neoplasm. Further, Applicant has provided no evidence or support that the claimed method is actually effective in treating neoplasms. In fact, the prior art is replete with examples of fibrates being administered, both *in vitro* and *in vivo*, to inhibit cancer cell proliferation or tumor growth. In almost all cases fibrates

were completely ineffective. Further still, the prior art suggests that fibrates actually cause cancer in some animal models.

The fact that Applicant has discovered a previously unknown mechanism of fibrate activity does not support the instantly claimed method of treating neoplasms without additional evidence that the claimed method is actually effective in treating cancer. As no nexus between aldose reductase activity and cancer cell growth has been demonstrated, the skilled artisan cannot readily extrapolate the data shown to the treatment of neoplasms.

4. The quantity of experimentation necessary

Because of the known unpredictability of the art (as discussed *supra*) and in the absence of experimental evidence commensurate in scope with the claims, the skilled artisan would not accept the assertion that the instantly claimed fibrates could be predictably used as a treatment for all neoplasms as inferred in the claims and contemplated by the specification. Mere recognition of a property of fibrates (in this case inhibition of aldose reductase) does not, *a priori*, provide enablement for the treatment of neoplasms with the claimed compounds. Accordingly, the instant claims do not comply with the enablement requirement of 35 U.S.C. § 112, first paragraph, since to practice the claimed invention a person of ordinary skill in the art would have to engage in undue experimentation, with no assurance of success.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 6-10 are rejected under 35 U.S.C. § 102(b) as being anticipated by Hirst *et al.* (Radiotherapy and Oncology, 1989, vol. 15, pages 55-61).

Hirst *et al.* teach that the antilipidemia drugs clofibrate and bezafibrate (instant claims 7 and 8) reduce the binding affinity of hemoglobin for oxygen and sensitize an experimental tumor (SCVII/St carcinoma) to radiation (Abstract; Figures 2, 3 and 4; Discussion). The drugs were administered at doses of 0.3 mmol/kg and 4.1 mmol/kg (pages 57-58).

The reference thus teaches administration of fibrates to an animal having a neoplasm in combination with radiation and therefore meets all of the limitations of the instant claims.

Claims 6-9 are rejected under 35 U.S.C. § 102(b) as being anticipated by Scatena *et al.* (Cell Death and Differentiation, 1999, vol. 6, pages 781-787).

Scatena *et al.* administered bezafibrate and gemfibrozil to the human leukemia-dreived cell lines HL-60, U-937 and K-562 (Abstract). The results show that these fibrates induce differentiation and significantly alter cell cycle distributions (Abstract; Figures 1-6).

The reference thus teaches contacting a neoplasm cell with a fibrate thereby meeting all limitations of the instant claims.

Claims 6 and 8-10 are rejected under 35 U.S.C. § 102(b) as being anticipated by Calais *et al.* (Radiotherapy and Oncology, 1991, vol. 22, pages 99-103).

Calais *et al.* teach that the antilipidemia drug clofibrate (instant claim 8) sensitizes *in situ* a mouse carcinoma (CaNT) to radiation (Abstract; Figures 1-3; Table 1; Discussion). The

authors conclude that clofibrate administration results in a significant increase in the sensitivity of a mouse carcinoma to radiation (page 103).

The reference thus teaches administration of a fibrate to an animal having a neoplasm in combination with radiation and therefore meets all of the limitations of the instant claims.

Claims 6 and 8-10 are rejected under 35 U.S.C. § 102(b) as being anticipated by Cohen (Clin. Investig., 1993, vol. 71, pages 74-77).

Instant claim 6 recites a method of treating neoplasms comprising administering a fibrate. Dependent claims limit the fibrate to gemfibrozil (claim 8) and the neoplasm to leukemia (claim 9). Dependent claim 10 recites an additional step comprising co-contacting the cell with a chemotherapeutic.

Cohen teaches the use of gemfibrozil in a patient with chronic myelogenous leukemia to manage retinoid-induced hypertriglyceridemia (Abstract). The leukemia patient was being treated with chemotherapeutics (interferon-α and cytarabine) thus meeting the limitation of instant claim 10 (page 72). Due to a rise in triglycerides, the patient was given gemfibrozil orally twice daily in addition to his current chemotherapy (page 75).

The reference thus teaches administration of a fibrate and chemotherapy to a patient having a neoplasm (leukemia).

Claims 6-7 and 9 are rejected under 35 U.S.C. § 102(b) as being anticipated by Kawamura *et al.* (Anticancer Research, 1999, vol. 19, pages 4099-4104) (cited by Applicant in IDS filed 4/21/2005; Citation A49).

Instant claim 6 recites a method of treating neoplasms comprising administering a fibrate. Dependent claims limit the fibrate to bezafibrate (claim 7) and the neoplasm to melanomas (claim 9).

Kawamura *et al.* teach the administration of bezafibrate to mice having B16 melanoma (Abstract; page 4100). Bezafibrate reduced B16 melanoma-induced cachexia (Figure 2) and triglyceride levels (Figure 3). Further, bezafibrate reversed the decrease in glucose and increase in non-esterified fatty acids induced by B16 melanoma (Figure 3).

The reference thus teaches administration of a fibrate (bezafibrate) to animals having a melanoma neoplasia.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James D. Anderson whose telephone number is 571-272-9038. The examiner can normally be reached on MON-FRI 9:00 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

James D. Anderson, Ph.D.
Patent Examiner
AU 1614

April 17, 2007

Phyllis Spivack

PHYLLIS SPIVACK
PRIMARY EXAMINER